DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 14, 2014

Fresenius Medical Care Renal Therapies Group, LLC
Denise Oppermann
Senior Director, Regulatory Affairs - Devices
920 Winter Street
Waltham, MA 02451

Re: K141281
Trade/Device Name: CRIT-LINE Clip (CLiC) Blood Chamber
Regulation Number: 21 CFR§ 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KOC
Dated: May 15, 2014
Received: May 16, 2014

Dear Denise Oppermann,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
N/A K141281

Device Name
CRIT-LINE Clip (CLiC) Blood Chamber

Indications for Use *(Describe)*
The CRIT-LINE Clip (CLiC) Blood Chamber is a sterile, single use, disposable, optical cuvette designed for use with the CLiC Monitor's sensor clip during acute and chronic hemodialysis therapy to non-invasively measure hematocrit, percent change in blood volume, and oxygen saturation. The blood chamber is connected between the arterial bloodline and the dialyzer within the extracorporeal circuit during hemodialysis treatment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 5. 510(K) SUMMARY

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR § 807.92.

## 5.1. Submitter's Information

**Name:** Fresenius Medical Care Renal Therapies Group, LLC
**Address:** 920 Winter Street
Waltham, MA
02451-1457
**Phone:** (781) 699-4479
**Fax:** (781) 699-9635
**Contact Person:** Denise Oppermann, Senior Director
Regulatory Affairs – Devices
**Preparation Date:** 5/15/2014

## 5.2. Device Name

**Trade Name:** CRIT-LINE Clip (CLiC) Blood Chamber
**Common Name:** CLiC Blood Chamber
**Product Code:** KOC
**Classification Panel:** Gastroenterology-Urology
**Classification Name:** Accessories, Blood Circuit, Hemodialysis
**Regulation:** 21 CFR 876.5820

## 5.3. Legally Marketed Predicate Device

CRIT-LINE Blood Chamber (K935958)

## 5.4. Device Description

The CRIT LINE™ Clip (CLiC) Blood Chamber is a non-invasive, disposable, transparent optical cuvette designed as a connection between the arterial bloodline and the hemodialyzer in the extracorporeal circuit during hemodialysis treatment. The chamber‘s two (2) polycarbonate viewing lenses serve to secure the CLiC Monitor‘s sensor clip and provide a uniform cross section, allowing a clear blood passage for the CLiC Monitor to transmit light through the blood. The CLiC Monitor uses the principle of light absorption to measure oxygen saturation (O2 SAT) and hematocrit (HCT) levels in the blood.

## 5.5. Comparison to Predicate

Table 1 contains a full description of the intended use and technological characteristics of the subject CLiC Blood Chamber as well as a comparison to the predicate CRIT-LINE Blood Chamber in each of these areas.

**Table 1: Device Description and Comparison to the Predicate**

| Feature | Predicate Device | Proposed Device | Comment |
|---|---|---|---|
| | CRIT-LINE Blood Chamber (K935958) | CLiC Blood Chamber | |
| Classification Product Code / Regulation | KOC/876.5820 | KOC/876.5820 | Substantially Equivalent |
| Indications for use | No Indications for Use statement was provided in K935958. | The CRIT-LINE Clip (CLiC) Blood Chamber is a sterile, single use, disposable, optical cuvette designed for use with the CLiC Monitor‘s sensor clip during acute and chronic hemodialysis therapy to non-invasively measure hematocrit, percent change in blood volume, and oxygen saturation. The blood chamber is connected between the arterial bloodline and the dialyzer within the extracorporeal circuit during hemodialysis treatment. | Substantially Equivalent |
| Configuration | A clear polycarbonate lens is sonically welded to a clear polycarbonate body. A secure connection with the arterial bloodline is made by a male Luer-lock connector. Connection to the hemodialyzer is made by a female conical fitting with external threads (DIN connector) which is part of the chamber body mold. Each connection is capped; caps are removed prior to treatment. | Two clear polycarbonate lenses are sonically welded to a translucent, blue polycarbonate body. A secure connection with the arterial bloodline is made by a male Luer-lock connector. Connection to the hemodialyzer is made by a polyvinylchloride (PVC), female conical fitting with external threads (DIN connector). Each connection is capped; caps are removed prior to treatment. | Substantially Equivalent |
| Blood Pathway | The blood pathway created by the CRIT-LINE Blood Chamber exposes the blood to only polycarbonate. | The blood pathway created by the CLiC chamber exposes the blood to three different materials; PVC (DIN connector), clear polycarbonate (lenses), and blue polycarbonate (chamber body). | Substantially Equivalent |
| Connection to Dialyzer | Female conical fitting with external threads.<br><br>Part of the chamber body mold. | Female conical fitting with external threads.<br><br>PVC component bonded to the chamber body mold with a bonding solution.<br><br>Meets ISO 594-2 performance requirements. | Substantially Equivalent |

**Table 1: Device Description and Comparison to the Predicate**

| Feature | Predicate Device | Proposed Device | Comment |
|---|---|---|---|
| | CRIT-LINE Blood Chamber (K935958) | CLiC Blood Chamber | |
| Connection to Arterial Bloodline | Male Luer-lock conical fitting with internal threads.<br><br>Part of the chamber body polycarbonate mold. | Male Luer-lock conical fitting with internal threads.<br><br>Part of the chamber body polycarbonate mold.<br><br>Meets ISO 594-2 performance requirements. | Substantially Equivalent |
| Connection Caps | Caps do not come into contact with the blood path and are discarded prior to treatment. | Caps do not come into contact with the blood path and are discarded prior to treatment. | Substantially Equivalent |
| Sensor Clip to Lens Interface | The predicate blood chamber includes a ―Double D" pattern molded into one side of the blood chamber. This shape matches the CRIT-LINE Monitor's sensor clip. The chamber guides the optical parts in the clip to the proper positioning relative to the viewing area and keeps the clip from rotating on the chamber. | Each lens employs a uniform annular ring to interface with the complementary shroud design of the CLiC Monitor's sensor clip. The shroud fills the area between the annular ring on the chamber and the outside edge of the lens. Each lens features an anti-rotation detent which interlocks with complementary tabs on both sides of the CLiC Monitor's clip. This prevents the rotation of the clip. | Substantially Equivalent |
| Sterilization Method | Gamma Radiation | Gamma Radiation | Substantially Equivalent |
| Pyrogenicity | Non-pyrogenic | Non-pyrogenic | Substantially Equivalent |
| Sterile Barrier | Unit Packaging | Unit Packaging | Substantially Equivalent |
| Single use or reuse | Single use only | Single use only | Substantially Equivalent |
| Packaging | Medical grade peel pouch with label information printed on the paper portion. | Blister pack made from medical paper with heat seal coating and a high performance nylon-based forming film pouch. Label information is printed on medical paper portion. | Substantially Equivalent |
| Biological Safety | Biologically Safe | Biologically Safe | Substantially Equivalent |

## 5.6. Performance Data

The following tables outline testing performed on the CLiC Blood Chamber to support the determination of substantial equivalence to the predicate device.

**Table 2: Performance and Functional Testing**

| Test Method | Test Objective | Result |
|---|---|---|
| Mechanical Characteristics / Structural Integrity | Ensure the blood chamber is capable of withstanding extreme positive and negative pressure conditions. | Pass – Results within acceptance criteria. |
| Dialyzer Connectors (Female Din connector) | Ensure the connectors meet the performance requirements of ISO 594-2. | Pass – Results within acceptance criteria. |
| Connector to Vascular Access Device (Male Luer Connector) | Ensure the connectors meet the performance requirements of ISO 594-2 | Pass – Results within acceptance criteria. |
| Endurance Performance Test:<br>Extracorporeal Circuit Evaluation | Demonstrate the product performs at various flow rates and bloodline-dialyzer combinations without resulting in any tubing failure (i.e. loosening of connections). | Pass – Results within acceptance criteria. |
| Endurance Performance Test:<br>Effects of Flow Rates on the CLiC Monitor Evaluation | Demonstrate varying flow rates do not affect the CLiC Blood Chamber‘s ability to allow the CLiC Monitor to record accurate and consistent measurements of Hematocrit (HCT) and Percent Oxygen Saturation (O2 Sat). | Pass – Results within acceptance criteria. |
| Endurance Performance Test:<br>Extracorporeal Circuit Evaluation of Maximum Flow Rate | Demonstrate the product performs at maximum flow rates without resulting in any tubing failure (i.e. loosening of connections). | Pass – Results within acceptance criteria. |
| Bond Strength Testing | Confirm the solvent bonding between the CLiC Blood Chamber blue polycarbonate body and the clear PVC DIN Connector. | Pass – Results within acceptance criteria. |
| Torque Test | Test the material properties after Gamma sterilization. | Pass – Results within acceptance criteria. |
| Blood Pathway Volume (Priming Volume) | Establish the blood pathway volume of the blood chamber for the information for use (IFU). | Pass – Results within acceptance criteria. |
| Functional CLiC Chamber Test | Evaluate the repeatability of the CLiC Blood Chamber by examining differences in hematocrit and oxygen saturation readings between individual chambers and multiple blood chamber lots. | Pass – Results within acceptance criteria. |
| Mechanical Hemolysis Test | Evaluate the hemolytic properties of the CLiC Blood Chamber when exposed to circulating blood flow. | Pass – Results within acceptance criteria. |

## Table 3: Packaging Qualification and Ship Testing

| Test Method | Test Objective | Results |
|---|---|---|
| Ship Testing (ISTA 1A) | Ensure the package design is robust and prevents product damage. | Pass – Results within acceptance criteria. |
| Bubble emission test | Ensure packaging does not yield any gross leaks. | Pass – Results within acceptance criteria. |
| Dye Penetration test | Ensure the porous medical packaging does not yield seal leaks. | Pass – Results within acceptance criteria. |
| Peel Test | Determine that the packaging meets the specification for the force required to separate the label portion of the packaging from film at the separator tab. | Pass – Results within acceptance criteria. |
| Film Tensile Strength | Determine that the film used on the packaging meets specification. | Pass – Results within acceptance criteria. |
| Microbial Barrier Aerosol Spore Challenge | Determine the passage of airborne bacteria through CLiC Blood Chamber packaging occurs at an acceptable level. | Pass – Results within acceptance criteria. |

## Table 4: Sterilization Validation Testing

| Test Method | Test Objective | Results |
|---|---|---|
| Sterilization Validation | Validate the gamma radiation sterilization process of the CLiC Blood Chamber by achieving a required sterility assurance level. | Pass – Results within acceptance criteria. |
| Bioburden Validation | Demonstrate the established sterilization dose maintains acceptable levels of bioburden. | Pass – Results within acceptance criteria. |
| Bacterial Endotoxins Test (Nonpyrogenicity) | Validate the claim of ~~n~~on-pyrogenic" on the device label. | Pass – Results within acceptance criteria. |

## Table 5: Additional Performance Testing

| Test Method | Test Objective | Results |
|---|---|---|
| Biological Safety | Demonstrate the biological safety of the CLiC Blood Chamber. | Pass – Results support the conclusion that the CLiC Blood Chamber is biologically safe. |
| Human Factors (Usability Testing) | Evaluate the use of the CLiC Blood Chamber in an environment representative of its intended use.<br><br>Determine if the instructions for use (IFU) allowed the intended user population to connect the CLiC Blood Chamber to the extracorporeal circuit correctly, safely, and effectively for its intended use. | Pass – Results support a conclusion that the CLiC Blood Chamber has no unacceptable residual risk and is safe and effective for use by the intended user population. |
| CLiC Blood Chamber Storage Temperature Test | Validate the storage temperature requirement on the device label. | Pass – Results within acceptance criteria. |

## 5.7. Conclusion

Based on a cumulative review of the verification and validation testing, the function of the CLiC Blood Chamber is substantially equivalent to the predicate CRIT-LINE Blood Chamber (K935958) and is safe and effective for its intended use.